



6-29-05

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PTO/SB/21 (02-04)

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>		Application Number	10/783,871
		Filing Date	February 20, 2004
		First Named Inventor	Bonnie HEPBURN
		Art Unit	1615
		Examiner Name	Thurman K. Page
Total Number of Pages in This Submission	10 + 1 CD	Attorney Docket Number	29635-714.201

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Technology Center (TC)
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
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<input type="checkbox"/> Certified Copy of Priority Document(s)	Remarks	
<input type="checkbox"/> Response to Missing Parts/Incomplete Application		
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SIGNATURE OF APPLICANT, ATTORNEY OR AGENT	
Firm or Individual name	Aubrey A. Haddach, Reg. No. 48,374, WILSON SONSINI GOODRICH & ROSATI
Signature	
Date	June 28, 2005

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as Express Mail (Label No. EV517732666 US) in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
Typed or printed name	Michael Boyd		
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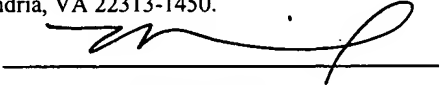
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PATENT

Attorney Docket No. 29635-714.201

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Patent Application of:	Group Art Unit: 1615
Applicant: Bonnie HEPBURN <i>et al.</i>	Examiner: Thurman K. Page
Serial No.: 10/783,871	<u>Certificate of Mailing Under C.F.R. §1.8</u>
Filed: February 20, 2004	I hereby certify that this correspondence and all marked attachments are being deposited by Express Mail, Express Mailing Label No. EV 517732666 US on 28-June 2005 addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
Title: <i>A Novel Formulation, Omeprazole Antacid Complex-Immediate Release Formulation for Rapid and Sustained Suppression of Gastric Acid</i>	 Michael Boyd

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is being submitted herewith on compact disc. The enclosed compact disc is being submitted as part of Applicants' Information Disclosure Statement and contains references cited on the respective PTO forms 1449. The information submitted in the compact discs is not intended to be part of the application and is not believed to be subject to 37 C.F.R. § 1.52(e). Applicants will resubmit copies of the references as necessary.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

This statement qualifies under 37 C.F.R. §1.97, subsection (b) because it is being filed before the mail date of the first Office Action on the merits.

- ☒ Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No.), copies are not enclosed herewith.
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
- ☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 29635-714.201).

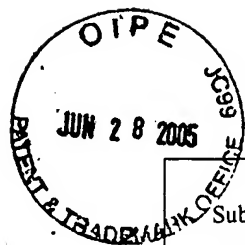
Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: June 28, 2005

By: Aubrey A. Haddach
Aubrey A. Haddach
Registration No. 48,374

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/783,871
				Filing Date	February 20, 2005
				First Named Inventor	Bonnie Hepburn
				Art Unit	1615
Examiner Name	Thurman K. Page				
Sheet	1	of	7	Attorney Docket Number	29635-714.201

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	1	US-5,997,903	12-07-1999	Dietrich et al.	
	2	US-6,551,621 B1	04-22-2003	Debregeas et al.	
	3	US-6,500,459	12-31-2002	Chhabra et al.	
	4	US-6,432,381	08-13-2002	Liversidge et al.	
	5	US-6,365,180 B1	04-02-2002	Meyer et al.	
	6	US-6,294,192 B1	09-25-2001	Patel et al.	
	7	US-6,569,463 B2	05-27-2003	Patel et al.	
	8	US-6,444,689 B1	09-03-2002	Whittle et al.	
	9	US-5,246,714	09-21-1993	Dahlinder et al.	
	10	US-6,555,139 B2	04-29-2003	Sharma	
	11	US-2002/0160046 A1	10-31-2002	Robinson et al.	
	12	US-2002/0044962 A1	04-18-2002	Cherukuri et al.	
	13	US-2002/0044960 A1	04-18-2002	Cherukuri	
	14	US-2001/0009678 A1	07-26-2001	Toshihiro et al.	
	15	US-2003/0096012 A1	05-22-2003	Besse et al.	
	16	US-2003/0091643 A1	05-15-2003	Friesen et al.	
	17	US-2003/0091630 A1	05-15-2003	Louie-Helm et al.	
	18	US-2003/0050620 A1	03-13-2003	Odidi et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ – Number ⁴ – Kind Code ⁵ (if known)				
	19	WO 02/085889 A1	10-31-2002	Hafner et al.		
	20	JP 2001040006	02-13-2001	Shimizu et al.		
	21	JP 2001-000406	01-09-2001	Yoshikazu et al.		
	22	WO 02/053097	07-11-2002	Taneja et al.		
	23	WO 01/28559 A1	04-26-2001	Eisai Co., Ltd.		
	24	WO 97/25066	07-17-1997	Depui et al.		

Examiner Signature	Date Considered
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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known		
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				Filing Date	February 20, 2005	
				First Named Inventor	Bonnie Hepburn	
				Art Unit	1615	
				Examiner Name	Thurman K. Page	
Sheet	2	of	7	Attorney Docket Number		29635-714.201

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		Number-Kind Code ² (if known)			
	25	US-2002/0068088 A1	06-06-2002	Gruber	
	26	US-2002/0039597 A1	04-04-2002	Ukai et al.	
	27	US-2002/0012680 A1	01-31-2002	Patel et al.	
	28	US-2002/0025342 A1	02-28-2002	Linder et al.	
	29	US-5,026,560	06-25-1991	Makino et al.	
	30	US-5,433,959	07-18-1995	Makino et al.	
	31	US-5,464,632	11-07-1995	Cousin et al.	
	32	US-6,328,994	12-11-2001	Shimuzu et al.	
	33	US-6,047,829	04-11-2000	Johnstone et al.	
	34	US-5,536,735	07-16-1996	Takechi et al.	
	35	US-5,635,520	06-03-1997	Uda	
	36	US-5,824,339	10-20-1998	Shimizu et al.	
	37	US-5,846,562	12-08-1998	Yanai et al.	
	38	US-5,948,773	09-07-1999	Akiyama et al.	
	39	US-6,169,102 B1	01-02-2001	Kanamaru et al.	
	40	US-6,299,904 B1	10-09-2001	Shimizu et al.	
	41	US-6,319,904	11-20-2001	Akiyama et al.	
	42	US-6,462,058 B1	10-08-2002	Fujishima et al.	
	43	US-6,586,004 B2	07-01-2003	Shimizu et al.	

FOREIGN PATENT DOCUMENTS						
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		Number-Kind Code ² (if known)			
	44	US-6,740,339 B1	05-25-2004	Ohkouchi et al.	
	45	US-2001/0009678 A1	07-26-2001	Toshihiro et al.	
	46	US-2001/00110825 A1	08-02-2001	Shimizu et al.	
	47	US-2001/0027192 A1	10-04-2001	Akiyama et al.	
	48	US-2002/0142034 A1	10-03-2002	Shimizu et al.	
	49	US 2003/0045724 A1	03-06-2003	Fujishima et al.	
	50	US 2003/0181487 A1	09-25-2003	Kamiyama et al.	
	51	US-2004/0005362 A1	01-08-2004	Taneja	
	52	US-2004/0018239 A1	01-29-2004	Ishida et al.	
	53	US-2004/0039027 A1	02-26-2004	Kamiyama et al.	
	54	US-2004/0048898 A1	03-11-2004	Fujishima et al.	
	55	US-2004/0049045 A1	03-11-2004	Hashimoto et al.	
	56	US-2004/0052854 A1	03-18-2004	Yoshinari et al.	
	57	US-2004/0082971 A1	04-29-2004	Fujishima et al.	
	58	US-2004/0097539 A1	05-20-2004	Terashita et al.	
	59	US-2004/0097555 A1	05-20-2004	Ohkawa et al.	
	60	US-2004/0131675 A1	07-08-2004	Yamamoto et al.	
	61	US-2003/0235628 A1	12-25-2003	Taneja et al.	
	62	US-2004/0006109 A1	01-08-2004	Taneja	
	63	US-2004/0081671 A1	04-29-2004	Taneja	

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		Number-Kind Code ² (if known)			
	64	US-2004/0081700 A1	04-29-2004	Taneja	
	65	US-2004/0082618 A1	04-29-2004	Taneja	
	66	US-2004/0121004 A1	06-24-2004	Taneja	
	67	US-2004/0131676 A1	07-08-2004	Taneja	
	68	US-2002/0146451 A1	10-10-2002	Sharma et al.	
	69	US-4,808,596	02-28-1989	Matsuishi et al.	
	70	US-2003/0096845 A1	05-22-2003	Whittle et al.	
	71	US-2003/0088106	05-08-2003	Whittall et al.	
	72	US-4,628,098	12-09-1986	Nohara et al.	
	73	US-4,689,333	07-25-1987	Nohara et al.	
	74	US-5,013,743	05-07-1991	Iwahi et al.	
	75	US-5,045,321	09-03-1991	Makino et al.	
	76	US-5,093,132	03-03-1992	Makino et al.	
	77	US-6,123,962	9-26-2000	Makino et al.	
	78	US-6,608,092	08-19-2003	Fujishima et al.	
	79	US-6,664,276	12-16-2003	Fujishima et al.	
	80	US-6,740,339	05-25-2004	Ohkouchi et al.	
	81	US-2001/0010825A1	08-02-2001	Shimizu et al.	
	82	US-2004/0082791A1	04-29-2004	Yoshinari et al.	
	83	US-2002/0192299A1	12-19-2002	Rajneesh et al.	

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[illegible][illegible]

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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	94	Dialog patent search re: omeprazole & specific coating, U.S. patents bibliographic – titles, claims, abstracts only, May 30, 2003, p. 1-211.	
	95	Dialog search re: omeprazole & specific coating, EP, PCT full text files, May 30, 2003, p. 212-804.	
	96	Dialog patent search re: omeprazole & specific coating, May 27, 2003, 154 pages.	
	97	Dialog patent search re: omeprazole & specific coating, May 29, 2003, 59 pages.	
	98	Nerac search re: Question No. 1116119.009, Omeprazole or Proton Pump Inhibitor and Coating (negate enteric)	
	99	Nerac search re: omeprazole and ethocel (ETC), Question No. 1116119.014, May 2003, 38 pages.	
	100	Nerac search re: omeprazole/microencapsulation/HP, Question No. 1116119.008, May 2003, 12 pages.	
	101	Nerac search re: omeprazole and RD100, Question No. 1116119.017, May 2003, 12 pages.	
	102	Nerac search re: omeprazole and (opadry or HPMC), Question No. 1116119.016, May 2003, 47 pages.	
	103	Nerac search re: omeprazole and kollicoat IR, Question No. 1116119.011, May 2003, 2 pages.	

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STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/783,871
				Filing Date	February 20, 2005
				First Named Inventor	Bonnie Hepburn
				Art Unit	1615
				Examiner Name	Thurman K. Page
Sheet	7	of	7	Attorney Docket Number	29635-714.201

NON PATENT LITERATURE DOCUMENTS			
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	104	Nerac search re: omeprazole and ethocel, Question No. 1116119.015, May 2003, 3 pages.	
	105	PHILLIPS, J.O. et al., "A Randomized, Pharmacokinetic and Pharmacodynamic, Cross-Over Study of Duodenal or Jejunal Administration Compared to Nasogastric Administration of Omeprazole Suspension in Patients at Risk for Stress Ulcers," American Journal of Gastroenterology (2001), Vol 96, No. 2, pp. 367-372.	

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